

Case No.: 1156.062  
Serial No.: 10/057,334  
October 3, 2002

### Remarks

Reconsideration of this application is requested. The election of Claims 4-10 is affirmed. Claims 4, 6, 7, 9, and 10 have been canceled without prejudice or acquiescence in the rejections (for instance, the allegation that "cardiac collapse" as taught in Ginsburg is the same thing as "cardiac arrest" comes unaccompanied by prior evidence). Of relevance to the only two claims remaining at issue (5 and 8) is that Claim 5 has been rejected as being obvious in light of Ginsburg and Clifton and Claim 8 has been rejected as being anticipated by Dato.

Claims 5 and 8 have been amended to explicitly recite limitations of Claim 4, which formerly had been implicitly recited.

Dato does not teach minimally invasive heart surgery, as recited in Claim 8. Dato teaches using its catheter pursuant to a thorectomy, col. 4, lines 15-30. No suggestion of a minimally invasive approach exists in Dato. This rejection has been overcome.

Claim 5 has been rejected under 35 U.S.C. §103 as being unpatentable over Ginsburg, used as a teaching of a cooling catheter but nowhere mentioning aneurysm surgery, in light of Clifton, used as a teaching of correcting an aortic aneurysm during profound hypothermia but failing to mention the use of heat exchange catheters.

Part of the prima facie case of obviousness is to explain why a likelihood of success exists for the proposed combination, MPEP §2142. In the present case, there is little likelihood of success that Ginsburg could be used for Clifton's purpose. Ginsburg col. 8, lines 50-52 teaches that the catheter is expected to have a temperature of no more than 20°C and, hence, could never cool a patient to the 8°-10°C range taught in Clifton. This would render a combination (in any event

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unsupported) of Ginsburg with Clifton not only unlikely to succeed at Clifton's purpose, but impossible for fulfilling it.

*Spec. to Clif.*  
While Ginsburg teaches that the catheter "could have" a temperature of zero degrees, consider that even with this temperature little likelihood of success exists for using Ginsburg to remove the relatively large quantity of heat that is necessary to induce the profound hypothermia envisioned by Clifton. The heat exchange applications for which Ginsburg was evidently designed require only cooling in relatively small body vessels and, hence, require a catheter that can get by with a heat removal capacity that might be far below that required to induce profound hypothermia. In fact, due to the engineering trade-offs that routinely exist in catheter design (usually relating to capacity versus size), one could reasonably expect that the size (and, hence, heat transfer capabilities) of Ginsburg would deliberately be as low as possible so that the Ginsburg catheter could be as small as possible to fit inside the blood vessels in which it is evidently intended to be placed. This would render a combination (in any event unsupported) of Clifton with Ginsburg unlikely to successfully undertake profound hypothermia.

Respectfully submitted,

  
John L. Rogitz  
Registration No. 33,549  
Attorney of Record  
750 B Street, Suite 3120  
San Diego, CA 92101  
Telephone: (619) 338-8075

**Marked up Version**

5. (amended) A method for treating a human patient, comprising the acts of: advancing a heat exchange catheter device into the patient; circulating coolant through the catheter device while preventing infusion of the coolant directly into the patient's bloodstream, the catheter device including at least one heat exchange region; and;  
performing aneurysm surgery while the patient's temperature is below normal body temperature.
  
8. (amended) A method for treating a human patient, comprising the acts of: advancing a heat exchange catheter device into the patient; circulating coolant through the catheter device while preventing infusion of the coolant directly into the patient's bloodstream, the catheter device including at least one heat exchange region; and;  
performing minimally invasive heart surgery on the patient while the patient's temperature is below normal body temperature.